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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Contact A. Corbin

Peripheral and Central Nervous System Drugs Advisory Committee; Notice
of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Peripheral and Central Nervous System Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on March 7, 2006, from 8 a.m. to 5 p.m.

Location: Holiday Inn Gaithersburg, The Ballrooms, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Sohail Mosaddegh, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301-827-7001, FAX: 301-827-6776, e-mail: mosaddeghs@cder.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512543. Please call the Information Line for up-to-date information on this meeting.

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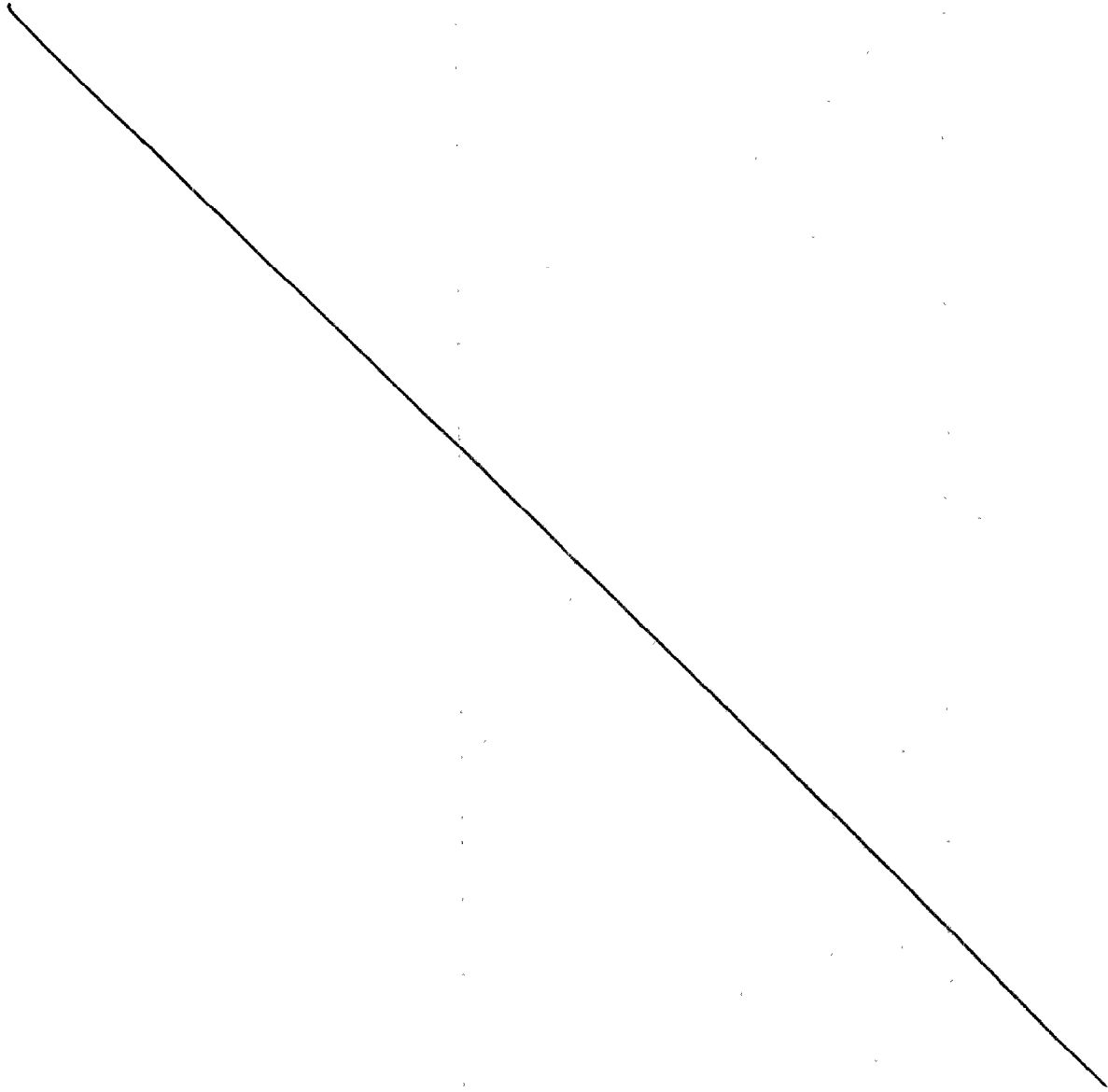
Agenda: The committee will discuss TYSABRI (natalizumab) biologic license application 125104/15; Biogen Idec Inc., for an indication in patients with relapsing forms of multiple sclerosis to reduce the frequency of clinical exacerbations. The committee will discuss the risks (including progressive multifocal leukoencephalopathy) associated with TYSABRI (natalizumab) administration, its efficacy in the treatment of multiple sclerosis relapses and/or disability, its possible return to the marketplace, and its proposed risk management plan(s).

The background material will become available no later than the day before the meeting and will be posted on FDA's Web site at <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm> under the heading "Peripheral and Central Nervous System Drugs Advisory Committee (PCNS)" (click on the year 2006 and scroll down to PCNS meetings.)

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by February 28, 2006. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 28, 2006, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

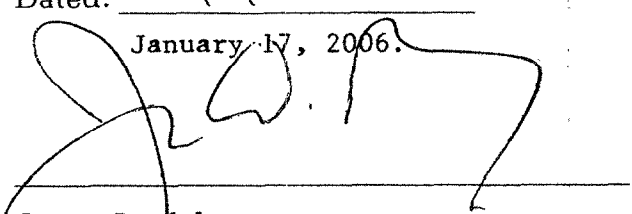
FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Sohail Mosaddegh at least 7 days in advance of the meeting.



Notice of this meeting is given under the Federal Advisory Committee Act
(5 U.S.C. app. 2).

Dated: 1.17.06

January 17, 2006.


Jason Brodsky,
Acting Associate Commissioner for External Relations.

[FR Doc. 06-????? Filed ??-??-06; 8:45 am]

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